REMARKS/ARGUMENTS

Claims 48-98, and 101-127 are pending in this application. Claims 69, 86-97, 101-119, and 125 have been withdrawn from consideration and claims 48, 123, 124 and 127 have been amended without prejuidice. Applicants reserve the right to pursue the previously presented claims in a continuation or divisional application.

Claim Rejections- 35 U.S.C. § 112

(i) Pluripotent Cells

The Examiner rejected claims 48-68, 70-85, 98, 120-124, 126 and 127 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement because the specification fails to provide teachings or guidance to show that the claimed hybrid cells are, indeed, pluripotent. Specifically, in the current Office Action, the Examiner rejects various elements of the claims as non-enabled based on the assertion that the specification fails to provide any other enabled use for hybrid mammalian cells, other than as pluripotent cells. Applicants point out that, as the Examiner has stated, the specification teaches that the hybrid cell can be maintained in an undifferentiated state and then can be induced to differentiate into a desired cell type, and can ultimately be used for transplantation. Also, as the Examiner points out, specifically in example 5, the Applicants were able to produce myocardial-like cells that were able to "beat", thereby demonstrating a utility which is the ability to differentiate the hybrid cell into cardiac-like cells. The reader need only be taught one method to carry out the claimed subject matter. As the Federal Circuit has held:

> [t]he purpose of [the enablement] provision is to assure that the inventor provides sufficient information about the claimed invention that a person of skill in the field of the invention can make and use it without undue experimentation, relying on the patent specification and knowledge in the art.

Scripps Clinic & Research Foundation v. Genentech, Inc., 18 USPQ2d 1001, 1006 (Fed. Cir. 1991)

Thus, the Applicants have enabled the invention as presently claimed.

(ii) Recipient Cells

The Examiner has also rejected claims 48-68, 70-85, 98, 120-124, 126 and 127 under 35 U.S.C. § 112, first paragraph on the basis that the claims are overbroad since the claims encompass methods of nuclear transfer utilizing any mammalian oocyte. To facilitate the prosecution of the present invention, Applicants have amended the claims to read "metaphase II oocyte" without prejuidice. Applicants reserve the right to pursue the previously presented claims in a continuation or divisional application.

Claim Rejections- 35 U.S.C. § 102

The Examiner has maintained the prior rejection of claims 47-57, 60-64, 66, 67, 70-74, 77, 78, 81, 82, 98, 123, 124, and 127 under 35 U.S.C. 102(b) as being anticipated by Peura (WO 98/29532). The Examiner noted in the prior Office action: "Peura's methods are directed to producing reconstituted embryos, and they particularly teach a method of, '[I]ncreasing cytoplasmic volume in an embryonic cell said method including providing at least two cytoplasts prepared by a method of enucleating an oocyte, providing an embryonic cell; and fusing said cytoplasts with the embryonic cell.' Thus, Peura teaches the production of more than one enucleated cytoplasts as a means to fuse at least two whole, enucleated cytoplasts, not the production of smaller, cytoplast fragments. The Examiner points out in the present Office action that the features upon which the Applicant relies (i.e., a decrease in the total amount of cytoplasm contributed by the cytoplast) were not recited in the previously pending claims. In response, Applicants have amended the claims to read:

> "A method of generating a hybrid mammalian cell comprising:
> (a) preparing more than one cytoplast fragment from a mammalian metaphase II oocyte or fertilized zygote wherein the amount of cytoplasm in the cytoplast fragment is less than the amount of cytoplasm in the mammalian oocyte;
> (b) obtaining a nuclear donor cell or karyoplast taken from a mammal;
> (c) combining a cytoplast fragment of step a) with the nuclear donor cell or karyoplast of step b) to produce a hybrid mammalian cell; and
> (d) if an oocyte is used in step (a), then activating the oocyte before, during or after step (c)."

Thus, the amended claims are not anticipated by Puera (WO 98/29532).

Conclusion

It is respectfully believed that this application is in condition for allowance. Early action is respectfully requested. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

No fees are believed to be due in connection with this response. However, should the Commissioner determine otherwise, he is authorized to charge such fees to Deposit Account No. 11-0980.

Respectfully submitted,

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